

Remarks

A. Status of Claims

Claims 21 and 22 have been amended. The amendment to claim 22 tracks a change made to claim 21. Claims 21-30 remain pending. No new matter has been added.

B. Examiner Interview Summary

On February 18, 2005, Applicants representative Michael Barrett phoned Examiners Young and Kishore. Dr. Russ Mumper and Dr. Michael Jay, the inventors, participated in the phone call. Applicants discussed the Yiv reference and particularly how it differs from the subject matter of the pending claims. For example, Applicants explained how the cited Yiv reference does not teach forming a microemulsion through heating and how Yiv does not form solid nanoparticles through a cooling step. After a detailed technical discussion, Examiner Kishore recommended that Applicants amend claim 21 to clarify the term “liquid nanoparticle matrix material.” Examiner Kishore explained that if this element more clearly indicated that a *solid material was melted to form the claimed microemulsion*, it would favorably address the current rejections. Applicants have adopted the Examiner’s suggestions, as detailed below. Applicants again wish to thank Examiners Young and Kishore for their time and attention to this file so that its prosecution can advance to issuance.

C. Section 102 Rejection

Claims 21-23, 25-27, and 30 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,245,349 (“Yiv”). In view of the claim amendments and following remarks, Applicants respectfully traverse.

Claim 21 has been amended as follows:

21. (currently amended) A method of making a solid nanoparticle, comprising:
making an oil-in-water microemulsion by heating, the microemulsion comprising:
a liquid nanoparticle matrix material formed by heating a solid matrix material until melted;
a surfactant or a co-surfactant or a mixture thereof, and
a molecule of interest; and
cooling the microemulsion to form the solid nanoparticle, where the molecule of interest is either entrapped in or adsorbed to the nanoparticle.

Amended claim 21 requires that the microemulsion include a liquid nanoparticle matrix material *formed by heating a solid matrix material until melted*. This clarification even further distinguishes claim 21 from the disclosure of Yiv. As confirmed with the Office through an interactive and careful review of Yiv's disclosure (including examples), Yiv nowhere discloses or suggests such an oil-in-water microemulsion. In particular, Yiv does not disclose melting a solid matrix material for making an oil-in-water microemulsion because Yiv, instead, produces oil-in-water microemulsions by diluting different materials that are liquid at room temperature. [See, e.g., Yiv, col. 6, lines 41-65; Example 1, cols. 9-10]. Yiv does not anticipate claim 21, and Applicants respectfully request removal of this rejection.

Claim 21 is not anticipated by Yiv for other, independent reasons. For example, Yiv does not disclose or suggest making the recited oil-in-water microemulsion *by heating*, as required by claim 21. As mentioned above, Yiv discusses forming an oil-in-water microemulsion by a *dilution* process: "The concentrated drug delivery compositions can be diluted with an aqueous fluid to form an oil-in-water microemulsion composition." [Yiv, Abstract; *also* Yiv, col. 2, lines 49-52 (stating, "The diluted form is prepared by adding an aqueous liquid, preferably water or a buffer solution, to the concentrated composition. The diluted oil-in-water microemulsions form spontaneously, without the need for high shear mixing equipment, upon the addition of the aqueous liquid to the concentrated compositions.")]. Yiv mentions a heating step only for the

purpose of dissolving a drug [Yiv, Example 3, col. 11; Example 7, col. 13] or to reduce viscosity of a concentrate [Yiv, col. 4, lines 34-39].

Yiv does not disclose or suggest *cooling* the recited microemulsion *to form a nanoparticle*, much less the recited *solid* nanoparticle. Instead, Yiv uses the term “nanoparticles” to refer to the oil-in-water microemulsions themselves, which are liquid-in-liquid systems. [Yiv, col. 5, lines 20-29]. In fact, Yiv admits that referring to the microemulsions as nanoparticles is not an appropriate description:

The diluted compositions are referred to herein as o/w microemulsions because there is a dispersed lipid (oil) phase within a continuous aqueous (water) phase. The lipid phase is primarily the active agent when an oil component is not used, and is the active agent and oil component when an oil component is used. These compositions can also be referred to as nanoparticle solutions, however the term microemulsion is considered more appropriate in view of the limitation on the upper end of the particle size range

[*Id.* (emphasis added)]. Disclosing a liquid-in-liquid microemulsion (even if inappropriately called a nanoparticle) does not amount to a disclosure or suggestion of claim 21’s requirement of cooling a particular type of microemulsion (absent in Yiv) to form a nanoparticle that is solid.

While claim 21 is believed to be allowable for the reason already considered by the Office and implemented by amendment to claim 21, it is also believed to be novel in view of at least the additional, significant differences outlined above. For the additional reasons as well, Applicants respectfully request removal of the current Section 102 rejection.

D. Section 103 Rejections

Dependent claims 24, 28, and 29 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious in view of Yiv. Applicants respectfully traverse. Rejected dependent claims 24, 28, and 29 are in condition for allowance for at least the reasons given above with respect to independent claim 21. The cited art does not disclose or suggest explicit elements required by claim 21.

E. Conclusion

Applicants believe that this submission fully responds to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so the claims may swiftly pass to issuance. Please contact the undersigned attorney at 512-536-3018 with any questions.